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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,726	08/24/2001	Jing-Shan Hu	PF112P3D1C1	3533

22195 7590 02/17/2004

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EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,726	HU ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/9/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *25 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An Office Action was mailed to Applicants on September 17, 2003 (Paper 17). However, Applicants submitted a preliminary amendment on September 9, 2003. Since the Office received the amendment prior to the mailing of the Action, that Action will be vacated in favor of this Action.

1. Formal Matters

A. Claims 1-76 are pending in the application and were subject to restriction in Paper No. 14, dated 6/4/03. In Paper No. 15, filed 6/27/03, Applicants elected Group I with traverse. Applicants argue that SEQ ID NO:18 (Group II) is identical to SEQ ID NO:2 except for the numbering. This argument has been considered and is deemed persuasive. Therefore, claims 1-76 will be examined. **HOWEVER**, it is brought to Applicants' attention that claims 74-76 recite polynucleotides, vectors and host cells, which should be restricted. However, since there are only 3 claims drawn to this Group, the Examiner has decided that it is not an undue burden to search these claims. However, if more claims are added, the Examiner may consider this an undue burden and restrict the polynucleotide claims from the polypeptide claims.

B. The Information Disclosure Statements, filed 1/25/02, has been entered into the record.

C. The Information Disclosure Statement, filed 1/30/02, has been entered into the record.

D. The Information Disclosure Statement, filed 3/12/02, has been entered into the record.

E. The Information Disclosure Statement, filed 4/18/02, has been entered into the record.

F. The Information Disclosure Statement, filed 8/16/02, has been entered into the record.

G. The Information Disclosure Statement, filed 9/12/02, has been entered into the record.

H. The Information Disclosure Statement, filed 6/20/03, has been entered into the record.

2. Information Disclosure Statement

A. References AM-AR on the IDS filed 1/25/02 have been lined through since US Applications not commonly assigned are not proper subject matter for an IDS.

Furthermore, reference DR on the IDS filed 1/25/02 has been lined through since no publication date has been provided.

C. References FN and FO on the IDS filed 1/25/02 have been lined through since International Search Reports are not proper subject matter for an IDS.

D. Reference FQ on the IDS filed 3/12/02 have been lined through since International Search Reports are not proper subject matter for an IDS.

3. Specification

A. The specification is objected to since the Brief Description of the Figures does not match the actual Figures. Specifically, the description of Figures 14, 16, 20 and 21 should recite, for example, "FIGS. 14A and 14B." This correction has been made by the Examiner for these Figures. However, Applicants may wish to amend the description to include a description of each of the separate panels for these Figures. This is optional. The description of Figure 25 has a similar issue. The Examiner amended the description to recite "FIGS. 25A-25O."

4. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 1-90 are provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application Nos. 09/219,442; 09/257,272; 09/623,725; 09/936,726; 10/060,523; 10/127,551. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. These applications were either not available to the Examiner at the time this Office Action was written, or had a large number of pending claims. However, the claims are known to be drawn to the proteins of SEQ ID NO:2 and 4, which are encoded for by the nucleic acid molecules of SEQ ID NO:1 and 3, respectively.

B. Claims 1-90 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over at least claims 1-15 of U.S. Patent No. 5,932,540. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the application and the patent recite various fragments of SEQ ID NO:2 and 4. For example the patent recites various fragments of SEQ ID NO:2 and 4, which would be encompassed by the present invention which claims fragments of at least 10, 30 or 50 residues of SEQ ID NO:2 or 4.

5. Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

A. Claims 11-14, 84 and 88-90 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5, 14 and 15 of prior U.S. Patent No. 5,932,540. This is a double patenting rejection. Both the application and the patent recite polypeptides at least 30 or 50 contiguous residues of SEQ ID NO:2 or 4, which are identical to those encoded for by ATCC No. 75968 and 97149.

6. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2, 4 and 18, does not reasonably provide enablement for fragments of these sequences comprising "at least 95% identity" to these SEQ ID NO:s, for polynucleotides encoding these proteins, or for fragments of "at least 10 contiguous residues" of these SEQ ID NOs. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to Applicants claiming all polypeptides which are **at least 95% identical** to SEQ ID NO:2, 4 or 18 and their encoding polynucleotides. Applicants have provided no guidance or working examples of any functional protein other than that of the full-length proteins of SEQ ID NO:2, 4 and 18, nor would it be predictable to the artisan how to make a functional protein which is less than the full-length of SEQ ID NO:2, 4 or 18. Applicants have not taught what critical residues must be retained in order to retain the function of the full-length proteins. Similarly, Applicants have not provided any guidance or working example of any fragments of SEQ ID NO:2, 4 or 18 which are "**10 or more contiguous amino acids**," including the function of those which migrate on an SDS-PAGE gel and those with specifically defined amino acids, such as "residues 61-74," for example. In claims 22-24, for example, Applicants do recite a function. However, again, Applicants have not taught what residues must be maintained in order to produce a protein with the desired functions, nor is it predictable to the artisan how to make proteins with these desired functions.

Therefore, in summary, the breadth of the claims is excessive with regard to Applicants claiming all polypeptides which are at least 95% identical to SEQ ID NO:2, 4 or 18, their encoding polynucleotides, or which are "10 or more contiguous amino acids," including the function of those which migrate on an SDS-PAGE gel and those with specifically defined amino acids, such as "residues 61-74," for example. Applicants have provided no guidance or working examples of any functional protein other than that of the full-length proteins of SEQ ID NO:2, 4 and 18, nor would it be predictable to the artisan how to make a functional protein which is less than the full-length of SEQ ID NO:2, 4 or 18. For these reasons, the Examiner holds that undue experimentation is required to practice the invention as claimed.

7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Polypeptides which are at least 95% identical to SEQ ID NO:2, 4 or 18, or which are "10 or more contiguous amino acids," including those which migrate on an SDS-PAGE gel and those with specifically defined amino acids, such as "residues 61-74," would have one or more amino acid substitutions, deletions, insertions and/or additions to the protein encoded for by SEQ ID NO:2, 4 and 18. Similarly, the encoding polynucleotides would also encode proteins with these amino acid alterations.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:2, 4 and 18, alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

8. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
February 11, 2004

ROBERT LANDSMAN
PATENT EXAMINER